9. (Amended) A composite material according to claim 8 wherein the compound with biological activity is selected from the group consisting of a pharmaceutically active substance, an insect repellent, a bactericide, a fungicide, an acaricide and mixtures thereof.

10. (Amended) A composite material according to claim 2 further comprising a second active ingredient dispersed in the emulsion.

11. (Amended) A method for preparing a composite material comprising:

(a) mixing a liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer; and

(b) extruding the mixture of (a) to form a composite material comprising a thermoplastic hydrophilic polymer matrix with the liquid active ingredient dispersed as inclusions of uniformly distributed droplets with a droplet size of between 0.01 μm to 2 μm in the matrix.

25. (Amended) A protective or controlled release system for an active ingredient comprising a composite material comprising a thermoplastic hydrophilic matrix and an active ingredient dispersed in a oil-in-water emulsion wherein the active ingredient forms inclusions of uniformly distributed droplets with a droplet size of between 0.01 μm to 2 μm in the matrix.

REMARKS

Claims 4, 6, 7, 8, and 10 have been amended to depend from claim 2. Support for these amendments is found in the specification in, for example, original claims 4, 6, 7, 8, and 10, respectively. *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 2 has been amended to explicitly recite all the limitations of the claim from which it depended (Claim 1). As is well settled, a claim in dependent form is construed to incorporate by reference all the limitations of the claim to which it refers. *See* 35 U.S.C. § 112. Accordingly, the scope of claim 2 has not been changed.

Claim 9 has been amended to correct the spelling of "acaricde." As is well settled, an amendment "to correct an error is not new matter if one skilled in the art would appreciate not only the existence of the error in the specification but what the error is." *Ex Parte Brodbeck*, 199 USPQ 230, 231 (Bd. App. 1977); *In re Oda*, 170 USPQ 268, 271 (CCPA 1971). This is just such a case. The above amendment merely corrects what is an obvious error. Accordingly, no change has been made to the scope of this claim.

Claims 11 and 25 have been amended to recite "with a droplet size of between 0.01 μm to 2 μm." Support for these amendments is found in the specification at, for example, page 8, lines 22-28; page 10, lines 17-20; Example 1; Figure 3; and in original claim 2. *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Objection

Claim 9 was objected to for containing an "typographical error in the [term] 'acaricide'." (Paper No. 3 at 2). As noted above, claim 9 has been amended to correct the spelling of "acaricide" and, it is submitted, the objection is rendered moot and should be withdrawn.

Indefiniteness Rejections

Claims 1-27 were rejected under 35 USC §112, second paragraph. (Paper No. 3 at 2). In making the rejection, the Examiner asserted that in claims 1, 11, and 25 "the term 'very fine', which is a term of degree, renders the claims vague and indefinite." (*Id.*). With a view toward furthering prosecution, claim 1 has been canceled, and claims 11 and 25 have been amended to recite "with a droplet size of between 0.01 μm to 2 μm." Accordingly, the rejection has been rendered moot and should be withdrawn.

Obviousness Rejection

Claims 1-27 were rejected under 35 USC §103(a) as being unpatentable over van Lengerich, U.S. Patent No. 6,190,591 B1 ("van Lengerich"), in view of Saleeb, *et al.*, Dev. Food Sci., 29, 651-663 (1992) ("Saleeb"), and Bilbrey, U.S. Patent No. 5,290,547 ("Bilbrey"). (Paper No. 3 at 3).

For the reasons set forth below the rejection, respectfully is traversed.

Van Lengerich discloses solid particles containing an encapsulated or embedded active ingredient. (Col. 7, lines 21-26). The particles contain a matrix material and an active ingredient. The matrix ingredient may be a polymer or a plasticizable biopolymer. (Col. 7, lines 54-60). The active ingredient may be pharmaceutically, biologically, or nutritionally active components. (Col 9, line 19 - col. 13, line 49). The active ingredient may coated with "film-building" or "film-forming" substances. Listed among those film-building or film-forming substances are emulsifiers. (Col. 9, line 62 - col. 14, line 9). The "thickness of the coating upon

the encapsulant may be used to control the rate of the release of encapsulant once the dissolving media, such as water, reaches the encapsulant." (Col. 14, lines 17-19).

Saleeb discloses "a method for fixing volatile oils/flavor ingredients in the form of droplets in homogeneous high density glassy substrates produced via a continuous melt extrusion process." (Pg. 651). An emulsifier may be employed to produce a "fine emulsion" when the volatile oil/flavor ingredient is mixed with the melted substrate. (Pp. 658-59).

Bilbrey discloses a method of making a microemulsion composition for controlling odors. (Abstract). The composition counteracts odors by application to the substrate of interest and is activated by moisture and mechanical action. (Col. 1, lines 61-64). The composition is a oil-in-water microemulsion of a viscous fragrance or aromatic oil dispersed in a water based solution. (Col. 2, lines 11-14). Microemulsion is further capable of being dried to form a rigid structure suspending droplets of the viscous fragrance or aromatic oil. (Col. 2, lines 15-17). In the microemulsion, the droplet size "may be from 2μ to 300μ but are preferably on the order of about 15 to 25μ in diameter. About 20μ is the most desirable size that any fracturing of the solidified material be likely to intersect oil droplets contained therein." (Col. 3, lines 22-26).

In making the rejection, the Examiner asserted that "van Lengerich teach controlled release particles which contain an encapsulated or embedded biologically or nutritionally or pharmaceutically active components in a plasticizable matrix, produced in a continuous process." (Paper No. 3 at 3). The Examiner acknowledged, however, that van Lengerich differs from the presently claimed invention in that "it fails to teach the specific types and components of the emulsion as required by the instant claims." (*Id.*).

To fill the acknowledged gap, the Examiner relied upon Saleeb to "teach method of encapsulating volatile oils or flavor ingredients in the form of fine emulsion droplets (1-50 microns in size) by continuous extrusion process." (*Id.*). The Examiner acknowledged, however, that even in combination van Lengerich and Saleeb differ from the presently claimed invention in that they "[lack] the teaching of the specific emulsifiers and surfactants of the instant claims." (*Id.*).

To fill the acknowledged gap, the Examiner relied upon Bilbrey to "[teach a] method to coat the oil-in-water emulsion droplets of fragrance oil for the use odor masking products." (*Id.*).

The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have ***looked to the prior art for specific teaching*** of making the inclusions in the form of oil-in-water microemulsion...." (*Id.* at 5). The Examiner also concluded "[i]t would also have been obvious to one skilled in the art to have chosen the emulsifiers and surfactants and optimized the HLB to obtain the fine dispersion of the droplets in the matrix...." (*Id.*).

Initially, we note that the rejection identifies Bilbrey (U.S. Patent No. 5,290,547) as one of the secondary documents upon which the rejection is based. The Bilbrey patent cited in Form PTO-892 and provided with the Office Action, however, is U.S. Patent No. 5,489,427. Thus it is not clear which patent is being used to reject the claims. As a matter of fundamental fairness, an applicant is entitled to know with clarity what is being used to reject the claims. MPEP §§ 707.05 and 707.05(e). For example, the examiner asserts that in Col. 4, lines 54-65, "[a]dding dextrin or polyvinyl alcohol, and sodium lauryl sulfate, sorbitan tristearate, sorbitan trioleate, or sorbitan monooleate for surfactants is disclosed." (Paper No. 3 at 4-5). No such

detailed disclosure is found in the '427 patent enclosed with the Office Action or cited in the Form PTO-892. Thus, for this reason alone, the rejection is insufficient as a matter of law, and should be withdrawn. It is further noted that should the Examiner maintain the rejection using the correct Bilbrey patent, the next Office Action must be non-final.

Furthermore, we also note that the rejection uses the wrong standard for determining obviousness. The rejection relies upon a "***look[] to the prior art for specific teaching***" standard that is not found in the statute or precedential authority. For this reason alone, the rejection should be withdrawn.

As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would ***impel*** one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection fails to provide any reason why one would be motivated, let alone impelled, to combine the references in the manner suggested by the Examiner.

Neither van Lengerich nor Saleeb disclose or suggest the use of a water-in-oil microemulsion, and Bilbrey does not disclose or suggest the encapsulation or suspension of the disclosed mircoemulsions. The Examiner has offered no evidence of anything in the documents which teach or suggest their combination. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. For this additional reason the rejection should be withdrawn.

Here, not only has the Examiner applied the wrong legal standard, which, it is submitted, is reason enough for withdrawal of the rejection (*see Ex parte Levengood*, 28 USPQ2d at 1301 (B.P.A.I. 1993)) and failed to provide evidence in any of the cited documents of

the motivation to combine in the manner suggested. Even if the documents were combined, however, they do not disclose or suggest all the elements of the instant claims. As is fundamental, "[t]o establish a *prima facie* case of obviousness ... the prior art reference must teach or suggest all the claimed limitations." *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); and MPEP 706.02(j), 2143, and 2143.03.

Van Lengerich discloses the use of emulsifier-coated active ingredients, but does not disclose or suggest the use of an oil-in-water emulsion. Indeed, van Langerich discloses only the use of "film-forming amounts of the [film-forming] substances in aqueous or alcoholic solutions or oleaginous compositions." (Col. 14, lines 6-9). "[T]he thickness of the coating upon the encapsulant may be used to control the rate of release of encapsulant once the dissolving media, such as water, reaches the encapsulant ... increasing the thickness of the coating on the encapsulant slows its rate of release into the media." (*Id.* at lines 16-24). Accordingly, van Lengerich discloses coating the active ingredient with a film-forming substance, not an oil-in-water microemulsion of the active substance.

Saleeb discloses a composition wherein an active ingredient is fixed in a high density glassy substrate. (Abstract). Saleeb further discloses the use of an emulsifier in the oil phase to produce a "fine emulsion when the oil phase is mixed with the melted substrate during extrusion." (Pp. 658-59). The "[E]xaminer takes the position that the reference implicitly teaches that these emulsion droplets are in the form of oil-in-water emulsion." (Paper No. 3 at 4). It is respectfully submitted that whatever position the Examiner "takes," the rejection must offer evidence to support that position. Nothing in Saleeb discloses or suggests an oil-in-water emulsion, and the rejection is absolutely devoid of any disclosure to the contrary.

Bilbrey discloses a method of making a microemulsion composition for controlling odors. (Abstract). In the microemulsion, the droplet size "may be from 2μ to 300μ but are preferably on the order of about 15 to 25μ in diameter. About 20μ is the most desirable size that any fracturing of the solidified material be likely to intersect oil droplets contained therein." (Col. 3, lines 22-26). Nothing in the rejection points to evidence that Bilbrey discloses or suggests a droplet size from 0.01μm to 2μm. In fact, Bilbrey suggests to one skilled in the art to use droplets of 2μm and ***larger***, *i.e.* up to 300μm. And, the rejection provides no evidence or reasoning why one skilled in this art would be motivated to use droplet sizes of from 0.01μm to 2μm given Bilbrey's disclosure of droplet sizes of 2μm to 300μm. Furthermore, the rejection fails to provide evidence that Bilbrey discloses or suggests the use of the microemulsion in combination with a matrix to form a composite material.

In sum, van Lengerich and Saleeb do not disclose or suggest the use of oil-in-water microemulsions, and Bilbrey does not disclose or suggest a "smaller" droplet size in the range of 0.01 μm to 2 μm, even though there is a single overlap in ranges at our high end and Bilbrey's low end. Thus, the documents when combined do not disclose or suggest all the claimed elements. And, as is fundamental, "[t]o establish a *prima facie* case of obviousness ... the prior art reference must teach or suggest all the claimed limitations." *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); and MPEP 706.02(j), 2143, and 2143.03. Accordingly, the examiner has not made out a *prima facie* case of obviousness, for this additional reason the rejection should be withdrawn.

For the reasons set forth above, the rejection is insufficient as a matter of fact and law. Accordingly, withdrawal of the rejection is respectfully requested.

In view of the foregoing, favorable action on the merits including entry of the amendments, withdrawal of the rejections and objection, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231, on November 29, 2001.

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Respectfully submitted,

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"Marked Up" Amendments to Claims Pursuant to Rule 1.121(c)

2. (Amended) A composite material comprising a thermoplastic hydrophilic matrix and a liquid active ingredient dispersed in an oil-in-water emulsion, wherein the liquid active ingredient forms inclusions in the matrix of uniformly distributed droplets, with [according to claim 1 wherein the inclusions have] a droplet size of between 0.01 μm to 2 μm.

4. (Amended) A composite material according to claim 2 [1] wherein a load of the active ingredient in the composite material is between 1 to 50 % w/w.

6. (Amended) A composite material according to claim 2 [1] wherein the active ingredient is selected from the group consisting of a flavor compound, an extract, a precursor or a composition containing a flavor compound, and mixtures thereof.

7. (Amended) A composite material according to claim 2 [1] wherein the active ingredient is selected from the group consisting of a fragrance, a fragrance precursor, an odor masking agent, and mixtures thereof.

8. (Amended) A composite material according to claim 2 [1] wherein the active ingredient is a compound with biological activity.

9. (Amended) A composite material according to claim 8 wherein the compound with biological activity is selected from the group consisting of a pharmaceutically active substance, an insect repellent, a bactericide, a fungicide, an acaricide [accaricide] and mixtures thereof.

10. (Amended) A composite material according to claim 2 [1] further comprising a second active ingredient dispersed in the emulsion.

11. (Amended) A method for preparing a composite material comprising:

(a) mixing a liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer; and

(b) extruding the mixture of (a) to form a composite material comprising a thermoplastic hydrophilic polymer matrix with the liquid active ingredient dispersed as inclusions of [very fine and] uniformly distributed droplets with a droplet size of between 0.01 μm to 2 μm in the matrix.

25. (Amended) A protective or controlled release system for an active ingredient comprising a composite material comprising a thermoplastic hydrophilic matrix and an active ingredient dispersed in a oil-in-water emulsion wherein the active ingredient forms inclusions of [very fine and] uniformly distributed droplets with a droplet size of between 0.01 μm to 2 μm in the matrix.